

PENDING CLAIMS:

1. (Currently amended) A method of making an oxidation and wear resistant medical implant, wherein the method comprises:
 - a) providing a polymeric material;
 - b) consolidating the polymeric material;
 - c) irradiating the consolidated polymeric material with ionizing radiation, thereby forming a consolidated and cross-linked polymeric material;
 - d) machining the consolidated and cross-linked polymeric material, thereby forming a medical implant; and
 - e) doping the medical implant with an antioxidant by diffusion, thereby allowing formation of a gradient of antioxidant in the consolidated polymeric material **of the medical implant, and thereby forming the oxidation and wear resistant medical implant, wherein the antioxidant is selected from the group consisting of an alpha-tocopherol, delta-tocopherol, tocopherol acetate, propyl gallate, octyl gallate, dodecyl gallate, lactic acid and a salt thereof, citric acid and a salt thereof, tartaric acid and a salt thereof, and orthophosphate.**
2. (Previously presented) The method of claim 1, wherein the oxidation and wear resistant medical implant is packaged and sterilized by ionizing radiation or gas sterilization.
3. (Originally presented) The method of claim 1, wherein the polymeric material is compression molded to another piece or a medical implant, thereby forming an interface or an interlocked hybrid material.
4. (Originally presented) The method of claim 1, wherein the consolidated polymeric material is compression molded to another piece, thereby forming an interface and an interlocked hybrid material.
5. (Previously presented) The method of claim 1, wherein the doping is carried out by soaking the medical implant in the antioxidant for about an hour to about 16 hours.

6. (Original) The method of claim 1, wherein the antioxidant is heated to about 100°C and the doping is carried out at 100°C.
7. (Original) The method of claim 1, wherein the antioxidant is heated to about room temperature and the doping is carried out at room temperature.
8. (Original) The method according to claim 1, wherein the cross-linked polymeric material is annealed at a temperature below the melt or above the melt of the consolidated and cross-linked polymeric material.
9. (Original) The polymeric material according to claim 1 is a polyolefin, a polypropylene, a polyamide, a poly ether ketone, or a mixture thereof.
10. (Original) The polyolefin of claim 9 is selected from a group consisting of a low-density polyethylene, high-density polyethylene, linear low-density polyethylene, ultra-high molecular weight polyethylene (UHMWPE), or a mixture thereof.
11. (Original) The method according to claim 1, wherein the implant comprises medical devices selected from the group consisting of acetabular liner, shoulder glenoid, pelvic component, finger joint component, ankle joint component, elbow joint component, wrist joint component, toe joint component, bipolar hip replacements, tibial knee inserts, tibial knee inserts with reinforcing metallic and polyethylene posts, intervertebral discs, sutures, tendons, heart valves, stents, vascular grafts.
12. (Previously presented) The method according to claim 1, wherein the polymeric material is polymeric resin powder, polymeric flakes, polymeric particles, or a mixture thereof.
13. (Original) The method according to claim 1, wherein the irradiation is carried out in an atmosphere containing between about 1% and about 22% oxygen.

14. (Previously presented) The method according to claim 1, wherein the irradiation is carried out in an inert atmosphere, wherein the inert atmosphere contains gas selected from the group consisting of nitrogen, argon, helium, neon, or a combination thereof.
15. (Original) The method according to claim 1, wherein the irradiation is carried out in a vacuum.
16. (Original) The method according to claim 1, wherein the cross-linked polymeric material is heated in an atmosphere containing between about 1% and about 22% oxygen.
17. (Original) The method according to claim 1, wherein the radiation dose is between about 25 kGy and about 1000 kGy.
18. (Original) The method according to claim 1, wherein the radiation dose is about 65 kGy, about 5 kGy, or about 100 kGy.
19. (Original) The method according to claim 1, wherein the radiation is a gamma irradiation.
20. (Original) The method according to claim 1, wherein the radiation is an electron beam irradiation.
21. (Original) The method according to claim 1, wherein reduction of free radicals in the cross-linked polymeric material is achieved by heating the polymeric material in contact with a non-oxidizing medium.
22. (Original) The method according to claim 1, wherein reduction of free radicals in the cross-linked polymeric material is achieved by contacting with a non-oxidizing medium and heating the medium to above the melting temperature of the cross-linked polymeric material.

23. (Original) The method according to claim 22, wherein the non-oxidizing medium is an inert gas.
24. (Original) The method according to claim 22, wherein the non-oxidizing medium is an inert fluid.
25. (Original) The method according to claim 22, wherein the medium is a polyunsaturated hydrocarbon selected from the group consisting of: acetylenic hydrocarbons such as acetylene; conjugated or unconjugated olefinic hydrocarbons such as isoprene and (meth)acrylate monomers; and sulphur monochloride with chloro-trifluoroethylene (CTFE) or acetylene.
26. (Original) The method according to claim 1, wherein reduction of free radicals in the cross-linked polymeric material is achieved by heating the polymeric material to a temperature above the glass transition point of the cross-linked polymeric material.
27. (Original) The method of claim 1, wherein the medical implant is soaked in a solution, containing about 50% by weight, of the antioxidant in ethanol.
28. (Original) The method of claim 1, wherein the medical implant is diffused with an antioxidant in a supercritical fluid.
29. (Original) The method of claim 28, wherein the supercritical fluid is CO₂.
30. (Original) The method according to claim 1, wherein the antioxidant is vitamin E.
31. (Original) The method according to claim 1, wherein the antioxidant is α -tocopherol.
32. (Original) The method of claim 1, wherein the medical implant is a non-permanent medical device.

33. (Original) The method of claim 32, wherein the non-permanent medical device is a catheter, a balloon catheter, a tubing, an intravenous tubing, or a suture.

34. (Currently amended) A method of making an oxidation and wear resistant medical implant, wherein the method comprises:

- a) providing a polymeric material;
- b) consolidating the polymeric material;
- c) machining the consolidated polymeric material, thereby forming a medical implant;
- d) irradiating the medical implant with ionizing radiation, thereby forming a cross-linked medical implant; and
- e) doping the medical implant with an antioxidant by diffusion, thereby allowing formation of a gradient of antioxidant in the consolidated polymeric material of the medical implant and thereby forming the oxidation and wear resistant medical implant, wherein the antioxidant is selected from the group consisting of an alpha-tocopherol, delta-tocopherol, tocopherol acetate, propyl gallate, octyl gallate, octadecyl gallate, lactic acid and a salt thereof, citric acid and a salt thereof, tartaric acid and a salt thereof, and orthophosphate

35. (Previously presented) The method of claim 34, wherein the oxidation and wear resistant medical implant is packaged and sterilized by ionizing radiation or gas sterilization.

36. (Original) The method of claim 34, wherein the polymeric material is compression molded to another piece or a medical implant, thereby forming an interface or an interlocked hybrid material.

37. (Original) The method of claim 34, wherein the consolidated polymeric material is compression molded to another piece, thereby forming an interface and an interlocked hybrid material.

38. (Original) The method of claim 34, wherein the doping is carried out by soaking the medical implant in vitamin E for about an hour or about 16 hours.

39. (Original) The method of claim 38, wherein the vitamin E is heated to about 100°C and the doping is carried out at 100°C.

40. (Original) The method of claim 38, wherein the vitamin E is heated to about room temperature and the doping is carried out at room temperature.

41. (Currently amended) A method of making an oxidation and wear resistant medical implant, wherein the method comprises:

- a) providing a polymeric material;
- b) consolidating the polymeric material;
- c) doping the consolidated polymeric material with an antioxidant by diffusion, thereby allowing formation of a gradient of antioxidant in the consolidated polymeric material, wherein the antioxidant is selected from the group consisting of an alpha-tocopherol, delta-tocopherol, tocopherol acetate, propyl gallate, octyl gallate, dodecyl gallate, lactic acid and a salt thereof, citric acid and a salt thereof, tartaric acid and a salt thereof, and orthophosphate;

d) crosslinking the antioxidant doped polymeric material, thereby forming an antioxidant doped polymeric material; and

e) irradiating the antioxidant doped cross-linked polymeric material by ionizing radiation, thereby forming the oxidation and wear resistant medical implant.

42. (Previously presented) The method of claim 41, wherein the oxidation and wear resistant medical implant is packaged and sterilized by ionizing radiation or gas sterilization.

43. (Original) The method of claim 41, wherein the polymeric material is compression molded to another piece or a medical implant, thereby forming an interface or an interlocked hybrid material.

44. (Original) The method of claim 41, wherein the consolidated polymeric material is compression molded to another piece, thereby forming an interface and an interlocked hybrid material.

45. (Original) The method of claim 41, wherein the doping is carried out by soaking the medical implant in vitamin E for about an hour or about 16 hours.

46. (Original) The method of claim 45, wherein the vitamin E is heated to about 100°C and the doping is carried out at 100°C.

47. (Original) The method of claim 45, wherein the vitamin E is heated to about room temperature and the doping is carried out at room temperature.

48. (Currently amended) A method of making an oxidation and wear resistant medical implant, wherein the method comprises:

- a) providing a polymeric material;
- b) consolidating the polymeric material;
- c) doping the consolidated polymeric material with an antioxidant by diffusion, thereby achieving formation of a gradient of antioxidant in the consolidated polymeric material, wherein the antioxidant is selected from the group consisting of an alpha-tocopherol, delta-tocopherol, tocopherol acetate, propyl gallate, octyl gallate, octyl gallate, lactic acid and a salt thereof, citric acid and a salt thereof, tartaric acid and a salt thereof, and orthophosphate;

- d) irradiating the antioxidant doped polymeric material by ionizing radiation, thereby forming an antioxidant doped cross-linked polymeric material; and

- e) packaging the antioxidant doped cross-linked polymeric material, thereby forming the oxidation and wear resistant medical implant.

49. (Previously presented) The method of claim 48, wherein the oxidation and wear resistant medical implant is packaged and sterilized by ionizing radiation or gas sterilization.

50. (Original) The method of claim 48, wherein the polymeric material is compression molded to another piece or a medical implant, thereby forming an interface or an interlocked hybrid material.

51. (Original) The method of claim 48, wherein the consolidated polymeric material is compression molded to another piece, thereby forming an interface and an interlocked hybrid material.

52. (Original) The method of claim 48, wherein the doping is carried out by soaking the medical implant in vitamin E for about an hour or about 16 hours.

53. (Original) The method of claim 52, wherein the vitamin E is heated to about 100°C and the doping is carried out at 100°C.

54. (Original) The method of claim 52, wherein the vitamin E is heated to about room temperature and the doping is carried out at room temperature.

55. (Currently amended) A method of making a sterile, oxidation and wear resistant medical implant, wherein the method comprises:

a) providing a polymeric material;
b) consolidating the polymeric material;
c) machining the consolidated polymeric material, thereby forming a medical implant;

d) doping the medical implant with an antioxidant by diffusion, thereby allowing formation of a gradient of antioxidant in the consolidated polymeric material of the medical implant, and thereby forming an antioxidant doped medical implant, wherein the antioxidant is selected from the group consisting of an alpha-tocopherol, delta-tocopherol, tocopherol acetate, propyl gallate, octyl gallate, dedecyl gallate, lactic acid and a salt thereof, citric acid and a salt thereof, tartaric acid and a salt thereof, and orthophosphate;

e) packaging the antioxidant doped medical implant; and
f) irradiating the packaged medical implant by ionizing radiation, thereby forming the sterile oxidation and wear resistant medical implant.

56. (Original) The method of claim 55, wherein the polymeric material is compression molded to another piece or a medical implant, thereby forming an interface or an interlocked hybrid material.

57. (Original) The method of claim 55, wherein the radiation dose is between about 25 kGy and about 150 kGy.

58. (Original) The method of claim 55, wherein the consolidated polymeric material is compression molded to another piece, thereby forming an interface and an interlocked hybrid material.

59. (Original) The method of claim 55, wherein the doping is carried out by soaking the medical implant in vitamin E for about an hour or about 16 hours.

60. (Original) The method of claim 59, wherein the vitamin E is heated to about 100°C and the doping is carried out at 100°C.

61. (Original) The method of claim 59, wherein the vitamin E is heated to about room temperature and the doping is carried out at room temperature.

62. (Currently amended) A method of making a sterile, oxidation and wear resistant medical implant, wherein the method comprises:

a) providing a polymeric material;
b) compression molding the polymeric material, thereby forming a medical implant;

c) doping the medical implant with an antioxidant by diffusion, thereby allowing formation of a gradient of antioxidant in the compression molded polymeric material of the medical implant, and thereby forming an antioxidant doped medical implant, wherein antioxidant is selected from the group consisting of an alpha-tocopherol, delta-tocopherol, tocopherol acetate, propyl gallate, octyl gallate, decyl gallate, lactic acid and a salt thereof, citric acid and a salt thereof, tartaric acid and a salt thereof, and orthophosphate;

d) packaging the antioxidant doped medical implant; and
e) sterilizing the packaged medical implant by ionizing radiation, thereby forming the sterile oxidation and wear resistant medical implant.

63. (Original) The method of claim 62, wherein the polymeric material is compression molded to another piece or a medical implant, thereby forming an interface or an interlocked hybrid material.
64. (Original) The method of claim 62, wherein the radiation dose is between about 25 kGy and about 150 kGy.
65. (Original) The method of claim 62, wherein the doping is carried out by soaking the medical implant in vitamin E for about an hour or about 16 hours.
66. (Original) The method of claim 65, wherein the vitamin E is heated to about 100°C and the doping is carried out at 100°C.
67. (Original) The method of claim 65, wherein the vitamin E is heated to about room temperature and the doping is carried out at room temperature.
68. (Original) The method according to claim 62, wherein the interlocked hybrid material is annealed at a temperature below the melt or above the melt of the cross-linked polymeric material.
69. (Original) The polymeric material according to claim 62 is a polyolefin, a polypropylene, a polyamide, a poly ether ketone, or a mixture thereof.
70. (Original) The polyolefin of claim 62 is selected from a group consisting of a low-density polyethylene, high-density polyethylene, linear low-density polyethylene, ultra-high molecular weight polyethylene (UHMWPE), or a mixture thereof.
71. (Original) The method according to claim 62, wherein the implant comprises medical devices selected from the group consisting of acetabular liner, shoulder glenoid, pelvic component, finger joint component, ankle joint component, elbow joint component, wrist joint component, toe joint component, bipolar hip replacements, tibial knee inserts, tibial knee inserts with reinforcing metallic and polyethylene posts, intervertebral discs, sutures, tendons, heart valves, stents, vascular grafts.

72. (Original) The method according to claim 62, wherein the polymeric material is in powder, polymeric flakes, polymeric particles, or the like, or a mixture thereof.

73. (Previously presented) The method according to claim 63, wherein the piece is metallic.

74. (Previously presented) The method according to claim 63, wherein the piece is a metal, a ceramic, or a polymer.

75. (Previously presented) The method according to claim 63, wherein the interface is a metal-polymer.

76. (Previously presented) The method according to claim 63, wherein the interface is a metal-ceramic.

77. (Currently amended) A method of making an oxidation and wear resistant medical implant, wherein the method comprises:

- a) providing a consolidated polymeric material;
- b) irradiating the consolidated polymeric material with ionizing radiation, thereby forming a consolidated and cross-linked polymeric material;
- c) machining the consolidated and cross-linked polymeric material, thereby forming a medical implant; and
- d) diffusing the medical implant with an antioxidant by diffusion, thereby allowing formation of a gradient of antioxidant in the consolidated **and cross-linked** polymeric material **on the medical implant**, and **thereby** forming the oxidation and wear resistant medical implant, **wherein the antioxidant is selected from the group consisting of an alpha-tocopherol, delta-tocopherol, tocopherol acetate, propyl gallate, octyl gallate, decyl gallate, lactic acid and a salt thereof, citric acid and a salt thereof, tartaric acid and a salt thereof, and orthophosphate.**

Claims 78-83. (Cancelled).

80. (Previously presented) The method according to claim 63, wherein the piece is non-metal
81. (New) The method according to claim 1, wherein the polymeric material is ultra high molecular weight polyethylene.
82. (New) The method according to claim 34, wherein the polymeric material is ultra high molecular weight polyethylene.
83. (New) The method according to claim 41, wherein the polymeric material is ultra high molecular weight polyethylene.
84. (New) The method according to claim 48, wherein the polymeric material is ultra high molecular weight polyethylene.
85. (New) The method according to claim 55, wherein the polymeric material is ultra high molecular weight polyethylene.
86. (New) The method according to claim 62, wherein the polymeric material is ultra high molecular weight polyethylene.
87. (New) The method according to claim 77, wherein the consolidated polymeric material is a high molecular weight polyethylene.
88. (New) The method according to claim 81, wherein the antioxidant is Vitamin E.
89. (New) The method according to claim 82, wherein the antioxidant is Vitamin E.
90. (New) The method according to claim 83, wherein the antioxidant is Vitamin E.
91. (New) The method according to claim 84, wherein the antioxidant is Vitamin E.

- 92. (New) The method according to claim 85, wherein the antioxidant is Vitamin E.
- 93. (New) The method according to claim 86, wherein the antioxidant is Vitamin E.
- 94. (New) The method according to claim 87, wherein the antioxidant is Vitamin E.